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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,616	03/10/2004	Richard W. Gross	15060-69	4077
69949 7590 07/09/2008 PATRICK W. RASCHE (15060) ARMSTRONG TEASDALE, LLP ONE METROPOLITAN SQUARE SUITE 2600 SAINT LOUIS, MO 63102-2740				
EXAMINER MOSS, KIRI A				
ART UNIT 1797		PAPER NUMBER		
NOTIFICATION DATE 07/09/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/797,616

Applicant(s)

GROSS ET AL.

Examiner

KERI A. MOSS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008 and 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 19-54 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I claims 1-17, 55 and 18 in the reply filed on April 17, 2008 is acknowledged. The traversal is on the ground(s) that the groups are related and that it would not be a serious burden on the examiner. This is not found persuasive because the different groups are located in different classes and subclasses and each group would require a different search. In addition, the non-elected inventions relate to either administration of a drug or testing with different drugs, which involves independent and distinct subject matter to the analysis in claim 1. Thus, the non-elected inventions would require an undue examination burden.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

2. The previous rejections under 35 USC 112, 2nd paragraph have been withdrawn in light of applicants' amendments and arguments.
3. With the exception of claim 18, the previous rejections under 35 USC 103 under Han et al in view of Koivusalo have been withdrawn in light of applicants' amendments and arguments.

Claim Rejections - 35 USC § 103

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Han et al. (Proc. Natl. Acad. Sci. USA, 1994) or Bragger et al. (Proc. Natl. Acad. Sci., USA, 1997) in view of Koivusalo et al. (J. Lipid Res., 2001).

Han discloses "electrospray ionization mass spectroscopic analysis of human erythrocyte plasma membrane phospholipids" involving linear regression analysis for correcting different instrumental efficiencies for molecular species.

Bragger teaches "quantitative analysis of biological membrane lipids at the low picomole level by nano-electrospray ionization tandem mass spectrometry", including ESI-MS/MS tandem spectrometry performed directly on extracts. Calibration functions are applied as described on page 2343, right column and Figure 7.

While Han and Bragger do not specifically disclose analysis of triglycerides, triglycerides are closely related to phospholipids of cell membranes. Han and Bragger do not specifically teach applying non-linear regression analysis for determining correlation functions for correcting efficiencies (sensitivities) of different molecular species.

Koivusalo teaches "quantitative determination of phospholipid compositions by ESI-MS: effects of acyl chain length, unsaturation, and lipid concentration on instrument response [species sensitivities, Ex.]" (Title). Koivusalo indicates that linearity of the instrument response can vary depending on the phospholipids acyl chain length, and linear correction function was applied for low total lipid concentrations, and at high total

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lipid concentrations the exponential (non-linear) regression function was indicated as better fitting the instrument response (see page 664, right column).

Therefore, it would have been obvious for any person of ordinary skill in the art to modify Han or Brugger's method using Koivusalo's results for non-linear response of ESI-MS instrument to lipids in high concentrations, for which non-linear regression fitting should be employed, because Han, Brugger and Koivusalo use analogous instruments and analytes.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-18 and 55 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-17 of application Serial No. 10/606601, now U.S. Patent 7,306,952. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The language of the claims differs only in

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the preamble of the independent claims as the claims of the '952 patent, wherein the '952 patent claims are for the determination of triglyceride, and the instant application claims are for the determination of lipid individual molecular species. The species "triglyceride" anticipates the genus "lipid individual molecular species."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797